13/589871 USSN Not yet assigned ROSCHER, et al. Page 1 of 7

## Appendix AP14 Rec'd PCT/PTO 18 AUG 2006 Claim Amendments

- 1. (Currently amended) A pharmaceutical formulation comprising а pharmaceutical acceptable salt glycopyrronium, a solvate solvates or physiologically functional derivative thereof in combination with ciclesonide, a pharmaceutically acceptable salt, solvate <del>solvates</del> physiologically functional or derivative thereof and a pharmaceutically acceptable carrier and/or one or more excipients, and optionally one or more other therapeutic ingredients.
- 2. (Currently amended) Formulation The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are contained in the same pharmaceutical formulation (fixed combination).
- 3. (Currently amended) Formulation The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are

contained in different pharmaceutical formulations (free combination).

4. (Currently amended) **Formulation** The formulation according to claim 1, comprising a compound selected from the group consisting of  $[11\beta, 16\alpha(R)] -$ -16,17-[(Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2 -methyl-1-oxopropoxy) pregna-1, 4-dien-3, 20-dion, [11 $\beta$ , 16  $\alpha(S)$ ]--16,17-[(Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxoprop-oxy)pregna-1,4-dien3,20-dion, [11**\beta**  $,16\alpha(R,S)]-16,17-[(Cyclohexyl$ methylen) bis (oxy) ]-11-hydroxy-21-(2-methyl-1-oxopropoxy)pregna-1,4-dien3,20-dion,  $16\alpha, 17-$ (22R)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1, 4-dien-3, 20-dion,  $16\alpha$ , 17-(22S)-Cyclohexylmethylendioxy- $11\beta$ , 21-dihydroxypregna-1, 4-dien-3, 20-dion and  $16\alpha, 17-$ (22R,S)-Cyclohexylmethylendioxy-11β,21-dihydroxypregna-1, 4-dien-3, 20-dion.

- 5. (Currently amended) Formulation The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is selected from [[form]] the group consisting of compounds racemic forms [S,S-, S,R, R,S- and R,R-forms]of the pharmaceutical acceptable salt of glycopyrronium in any mixing ratio and enantiomerically enriched S,S-, S,R,R,S- and R,R-forms of the pharmaceutical acceptable salt of glycopyrronium.
- 6. (Currently amended) Formulation The formulation according to claim 5, wherein the enantiomerically enriched form of the pharmaceutical acceptable salt of glycopyrronium is the R,R-form (i.e. (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium).
- 7. (Currently amended) Formulation The formulation according to claim 6, wherein the R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess (ee), preferably 95% ee, more preferably more than 98% ee, and in particular preferably more than 99.5% ee.

- 8. (Currently amended) Formulation The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide, which substantially does not contain glycopyrronium in the S,S-, S,R-and/or R,S- forms.
- 9. (Currently amended) Formulation The formulation according to claim 1, comprising pharmaceutical acceptable salt of glycopyrronium and ciclesonide in an amount and ratio to be effective for a twice or once daily treatment of a clinical condition in a mammal, such as a human, for which a corticosteroid and/or an anticholinergic agent is indicated.
- 10. (Currently amended) Formulation The formulation according to claim 1, which is suitable for administration by inhalation.

- 11. (Currently amended) Formulation The formulation according to claim 1, which is suitable for nasal administration.
- 12. (Currently amended) Pharmaceutical The formulation according to claim 1, which is a dry powder and the carrier is a saccharide.
- 13. (Currently amended) Pharmaceutical The formulation according to claim 12, wherein the carrier is lactose monohydrate.
- 14. (Currently amended) Method for the prophylaxis or A method of treatment of a clinical condition in a mammal, such as a human, for which a corticosteroid and/or an anticholinergic agent is indicated, which comprises administration of therapeutically a effective amount of a pharmaceutical formulation comprising ciclesonide or a pharmaceutical acceptable salt, solvate, or physiologically functional derivative thereof in combination with pharmaceutical acceptable salt of glycopyrronium, a solvate, or physiologically functional derivative

thereof, and a pharmaceutical acceptable carrier and/or one or more excipients.

- 15. (Currently amended) Method The method according to claim 14, wherein the clinical condition is selected from the group consisting of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic bronchitis, [[and]] wheezy bronchitis, emphysema, [[,]] shortness of breath, respiratory tract infection, [[and]] upper respiratory tract disease, rhinitis, allergic rhinitis and seasonal rhinitis.
- 16. (Currently amended) Method The method according to claim 15, which comprises a twice daily dosage regimen.
- 17. (Currently amended) Method The method according to claim 15, which comprises a once daily dosage regimen.
- 18. (Currently amended) Method The method according to claim 15, which comprises administration of a combination of [[the]] a pharmaceutical acceptable

salt of glycopyrronium and ciclesonide in the same administration form by inhalation from an inhaler and wherein each actuation provides a dose therapeutically effective for a twice daily dosing regiment or for a once daily dosing regiment.

19. (Currently amended) Dry A dry powder inhalation product comprising a pharmaceutical composition according to claim 13.